UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PAMELA S. SILVEY, et al., Plaintiffs, v. SMITHKLINE BEECHAM CORP., Defendant.	CASE NO. C-1-01-164 JUDGE HERMAN J. WEBER **DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

Defendant SmithKline Beecham Corp. (SmithKline) moves for summary judgment on all of plaintiffs' claims pursuant to Federal Rules of Civil Procedure 56(b), 56(c) and Local Rule 7.2. SmithKline is entitled to summary judgment because reasonable minds could only conclude that plaintiff Pamela Silvey *did not use* a SmithKline product containing phenylpropanolamine ("PPA") during the events in question. Both Pamela Silvey and her husband were exhaustively interviewed regarding medication use during the events in question, and both consistently *denied* that Mrs. Silvey had been using any medications. (*See* citations, *infra.*) Moreover, *all* of the contemporaneous medical records establish that Mrs. Silvey was not taking any medications during the events in question. Further, as to plaintiffs' failure to warn claim, this claim fails because plaintiff admitted that she never read any product warnings. (*See infra.*) Accordingly, there can be no genuine issue of material fact, and SmithKline is entitled to summary judgment in its favor as a matter of law. A memorandum in support of this motion is attached, along with supporting deposition testimony, exhibits and Proposed Findings of Fact and Conclusions of Law.

Respectfully submitted,

/s/ ROBERT C. TUCKER
ROBERT C. TUCKER, Trial Attorney (0013098)
email: rtucker@tuckerellis.com
EDWARD E. TABER (0066707)
email: etaber@tuckerellis.com
TUCKER ELLIS & WEST LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, OH 44115-1475
Telephone: (216) 592-5000
Telefax: (216) 592-5009

Attorneys for Defendant
SmithKline Beecham Corporation

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PAMELA S. SILVEY, et al., Plaintiffs, v. SMITHKLINE BEECHAM CORP., Defendant.	CASE NO. C-1-01-164 JUDGE HERMAN J. WEBER **MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

I. STATEMENT OF FACTS

A. Background Facts

This pharmaceutical product liability action was filed by plaintiffs Pamela and Kenneth Silvey in the United States District Court, Southern District of Ohio (Cincinnati) on March 19, 2001. There is one defendant -- SmithKline Beecham Corp.

Plaintiffs claim that Mrs. Silvey was injured by over-the-counter Contac® cold medicine manufactured by SmithKline, which she allegedly ingested on January 15, 1998. Plaintiffs allege that the Contac® cold medicine in question contained phenylpropanolamine ("PPA"). Plaintiff Kenneth Silvey (Pamela Silvey's husband) alleges a derivative loss of consortium claim.

Defendant denies that Mrs. Silvey ingested any PPA-containing SmithKline product, and affirmatively states that her injury (a stroke) was caused by the rupture of a congenital blood-vessel abnormality (a cerebral aneurysm), aggravated by her history of heavy smoking, not by PPA. SmithKline also affirmatively states that any PPA-containing Contac® products were not defective in any way, and that many Contac® products never contained PPA.

B. Pertinent Medical Facts

Mrs. Silvey was admitted to Good Samaritan Hospital in Cincinnati, Ohio on January 15, 1998, after she was involved in an automobile accident. Harry Van Loveren, M.D. was her treating physician. She was diagnosed with a type of stroke known as a "subarachnoid hemorrhage." (Deposition of Harry Van Loveren, M.D., taken October 24, 2003, at pp. 26-27, Exhibit A.)("Dr. Van Loveren depo.") This subarachnoid hemorrhage was the result of a ruptured aneurysm[1] in her brain. (*Id.* at 13, 18-19, 26-27.) In retrospect, Mrs. Silvey's aneurysm had been present for many years, probably since birth. (*Id.* at pp. 19-20, 22, Exhibit A) After Mrs. Silvey's arrival at Good Samaritan Hospital on January 15, 1998, her husband was interviewed multiple times regarding whether Mrs. Silvey had been taking any medications. (*Id.* at pp. 8-15.) At least four separate medical histories were obtained on January 15, 1998, by different medical personnel, and *each time* medications were discussed, these medical providers were told that Mrs. Silvey *had not been taking any medications*. (*Id.* at pp. 8-14.) These medical providers would typically ask about both prescription and non-prescription drug use. (*Id.* at p.11.) There is *not a single reference* in any of Mrs. Silvey's Good Samaritan Hospital records to indicate that she ever used *any* medication prior to her stroke on January 15, 1998. (*Id.* at p. 37.) Her treating surgeon similarly confirmed that there is no evidence in the contemporaneous medical records to suggest that any medication Mrs. Silvey took on January 15, 1998 caused her stroke. (*Id.* at p. 28.)

While under Dr. Van Loveren's care for her stroke, Mrs. Silvey voluntarily enrolled in medical studies conducted by Cincinnati neurologist Joseph Broderick, M.D. (Dr. Van Loveren depo. at pp. 32-35, Exhibit A.) The purpose of Dr. Broderick's research was, in part, to investigate various potential causes of stroke, including PPA use and cigarette smoking. Mrs. Silvey had a

[1] An aneurysm is a structural, often congenital weakness in the wall of a blood vessel whereby the walls of the vessel enlarge slowly over time, and can ultimately rupture. The type of stroke that Mrs. Silvey had, a "subarachnoid

history of smoking 1-2 packs per day beginning at age 14. (Deposition of Plaintiff Pamela Silvey, taken December 18, 2002, at p. 180, Exhibit B.)("Pamela Silvey depo.") Mrs. Silvey and her husband signed consent forms on February 13, 1998 authorizing her participation in Dr. Broderick's studies. (Exhibit C)(*See also* Dr. Van Loveren depo at pp. 35-36, Exhibit A.) One of these studies became known as the "Yale Study."

During the course of these medical studies, both Pamela Silvey and her husband, Kenneth Silvey, were interviewed exhaustively by Dr. Broderick's research nurse, Laura Sauerbeck, R.N., regarding whether Mrs. Silvey had been taking any prescription or non-prescription medications prior to her stroke. (Deposition of Laura Sauerbeck, R.N., taken March 13, 2003, at pp. 20, 33, Exhibit D)("Nurse Sauerbeck depo.") Each detailed individual interview lasted between thirty and forty-five minutes. (*Id.* at p. 29.) Specifically, Nurse Sauerbeck interviewed plaintiff Pamela Silvey on February 13, 1998, and plaintiff Kenneth Silvey on February 14, 1998. (*Id.* at pp. 20, 40-41.) According to Nurse Sauerbeck, extraordinary precautions were taken during these interviews to ensure that thorough and accurate information regarding prescription and non-prescription medication usage was obtained, and that the interviewees were fully competent to answer any and all questions. (*Id.* at pp. 39-40, 76-77)(*See also* Dr. Van Loveren depo. at p. 48, Exhibit A.) One of the purposes of these studies was to investigate a potential link between PPA-containing medications and stroke, so numerous questions designed to ferret-out PPA product use were asked during the interviews, and product photographs were routinely provided to assist interviewees in identifying any PPA-containing products that they may have used. (Nurse Sauerbeck depo. at pp. 48-49, 64, Exhibit D.)

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hemorrhage related to a cerebral aneurysm," has been strongly associated with smoking. (*See* Deposition of Harry Van Loveren, M.D., pp. 39-40, Exhibit A.)

Significantly, during these interviews, both Pamela Silvey and Kenneth Silvey *specifically denied* that Mrs. Silvey had been using any such PPA-containing medications. (Nurse Sauerbeck depo. at pp. 33, 43, 49-50, 52-53, 60, 78, Exhibit D.) These denials were contemporaneously documented by Nurse Sauerbeck in Mrs. Silvey's case file, and these questionnaires are attached hereto as Exhibit E. (*See also* Nurse Sauerbeck depo. at pp. 27, 41, Exhibit D.)

Following her hospitalization in January and February of 1998, Mrs. Silvey made a full recovery, and was back to work (full time, and with no restrictions) within six months of her stroke. (Dr. Van Loveren depo. at pp. 23-26, Exhibit A.) Mrs. Silvey does not claim *any* residual or permanent injuries as part of this lawsuit. (Pamela Silvey depo. at p. 204, Exhibit B.)

C. Initiation Of The Lawsuit

Almost three years later, in November of 2000, Mrs. Silvey received a letter from Dr. Broderick thanking her for her participation in the stroke studies. (Pamela Silvey depo. pp. at 17-18, Exhibit B.) Dr. Broderick's letter also noted that some of his research might indicate a potential link between some PPA-containing products and certain injuries. (*Id.*) Shortly thereafter, according to Mrs. Silvey's own testimony, she viewed a plaintiff's lawyer commercial on television advertising for PPA claims against various pharmaceutical companies. (*Id.* at pp. 94-95; 100-101.) Then, Mrs. Silvey retained counsel and this lawsuit followed. (*Id.* at pp. 17-18, 94-95; 100-101.) Despite the exhaustive, contemporaneous medical histories and interviews wherein Mrs. Silvey and her husband *specifically denied* that she had been using PPA-containing products prior to her stroke, plaintiffs now claim precisely the opposite. (*See* Plaintiff's Complaint, filed March 19, 2001.)

In June of 2003, Dr. Broderick published a focused analysis of his research regarding hundreds of patients with strokes similar to Mrs. Silvey's (*i.e.* aneurysmal subarachnoid hemorrhage). Presumably, this study was based, in part, on Mrs. Silvey's case. (Dr. Van Loveren depo. at pp. 37-39, Exhibit A.) This paper concluded that a history of heavy smoking was strongly

associated with aneurysmal subarachnoid hemorrhage. (*Id.* at pp. 39-41.) This study also found *no association whatsoever* between PPA products and Mrs. Silvey's type of stroke. (*Id.* at p. 40.)

D. Procedural Posture

This suit was originally filed on March 19, 2001 in U.S. District Court for the Southern District of Ohio. On September 27, 2001, this Court entered a stay of proceedings, and shortly thereafter, this case was transferred to the United States District Court, Western District of Washington for multi-district litigation pretrial proceedings. (MDL No. 1407). Discovery proceeded in the MDL, and this matter was remanded by an Order/Suggestion of Remand signed by Judge Barbara Jacobs Rothstein of the Western District of Washington at Seattle, filed with this Court on March 16, 2004.

II. LAW AND ARGUMENT

A. The Summary Judgment Standard

Summary judgment must be entered against a party who fails to make a showing sufficient to establish an essential element of that party's case, and on which that party will bear the burden of proof at trial. *Ste. Marie v. City of Dayton*, 162 F. Supp. 2d 766, 767 (S.D. Ohio 2001), *citing Celotex v. Catrett*, 477 U.S. 317, 322 (1986).

The moving party bears the initial responsibility of informing the District Court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, to support its motion. *Ste. Marie*, 162 F. Supp. 2d at 767.

The burden then shifts to the non-moving party, who must set forth specific facts showing that there is a genuine issue for trial. *Ste. Marie*, 162 F. Supp. 2d at 767, *citing Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). Once the burden has shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations, nor is it sufficient

to simply show that there is some metaphysical doubt as to the material facts. *Ste. Marie*, 162 F. Supp. 2d at 767, *quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986). The party opposing summary judgment must present more than a "scintilla of evidence" in support of its position. *Ste. Marie*, 162 F. Supp. 2d at 767, *quoting Michigan Protection and Advocacy Service, Inc. v. Babin*, 18 F.3d 337, 341 (6th Cir. 1994). Summary judgment shall then be entered if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Ste. Marie, supra*; Fed. R. Civ. P. 56(c).

B. The Summary Judgment Standard As Applied To This Case

In this case, plaintiffs' late-blooming uncorroborated claim -- after watching a lawyer's advertisement on television -- that she was taking a PPA-containing product at the time of her stroke almost three years earlier, provides (at the very most), a "scintilla of evidence" that she in fact did so. But, that's not enough. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). That scintilla is not only outweighed, but is also directly contradicted by the undisputed contemporaneous medical records *and the contemporaneous statements of the plaintiffs themselves,* which establish that Pamela Silvey *did not use* SmithKline's product during the events in question. Under these circumstances, no *reasonable* jury could conclude that Mrs. Silvey truly used SmithKline's PPA-containing product in 1998.

This evaluation of the summary judgment evidence, if only to determine whether there is more than one "reasonable conclusion" to be drawn, is exactly what the Court is expected to do in such a case as this. For example, in *Anjeski v. ACandS Inc.*, the Sixth Circuit upheld summary judgment in a product liability case where the plaintiff's "product identification" evidence was exceptionally weak, just as in the case at bar. *Anjeski v. ACandS Inc.*, No. 89-1571, 1990 WL 58191 (6th Cir. May 7, 1990) (unpublished opinion)(Exhibit F). The *Anjeski* court noted that: "[T]he threshold requirement of any

products liability action is identification of the injury-causing product and its manufacturer." *Anjeski*, 1990 WL 58191 at **4. Although the plaintiff in the *Anjeski* case produced some weak evidence of product identification, the district court concluded that "a jury would have to take several long, speculative leaps from [plaintiff's] testimony" to find that the plaintiff was exposed to the defendant's products. *Anjeski*, 1990 WL 58191 at **4.

In upholding summary judgment for the defendant-manufacturer, the Sixth Circuit stated as follows in *Anjeski*:

> A federal court's evaluation of a motion for summary judgment necessarily involves weighing the evidence and the inferences drawn therefrom to determine whether a *genuine* issue of *material* fact exists. The mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. [O]nly by determining whether the evidence "preponderates" can a district court decide whether there is more than one reasonable conclusion to be drawn from the material facts.

Anjeski, 1990 WL 58191 at **3, *citing Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original)(citations omitted)(Exhibit F).

Similarly, in the pharmaceutical product liability context, the Sixth Circuit upheld summary judgment under similar circumstances in *Dawson v. Bristol Laboratories*, 658 F. Supp. 1036 (6th Cir. 1987). In *Dawson*, the court granted summary judgment for the defendant-manufacturer of the drug tetracycline, despite plaintiff's claim to have used defendant's product. *Id.* As with plaintiffs herein, the *Dawson* court noted that plaintiff's contradictory memory regarding product identification *did not raise a genuine issue of material fact*:

> In response, plaintiffs suggest that even though they remember the tetracycline as red, orange or pink, and in clear containers, it is possible that their recollection is erroneous. Specifically, plaintiffs state at page 5 of their response brief: *"It is quite obvious that distorted memory could have produced recollection concerning coloration which is at variance with the colorations appending Upjohn's Tetracycline syrups. In any event it is a questions (sic) of fact…"*

Dawson, 658 F. Supp. at 1042-43. The *Dawson* court rejected this attempt by plaintiff to create an issue of fact arising from plaintiff's memory inconsistencies, just as the Court should reject in the case at bar.

And, in litigation involving the drug diethylstilbestrol (DES), both the Sixth Circuit and the Ohio Supreme Court construed Ohio's product liability laws as *requiring* plaintiffs in pharmaceutical product liability claims to offer competent evidence establishing that the plaintiffs had ingested the specific product manufactured by the defendant. *See, e.g. Kurczi v. Eli Lilly & Co.*, 113 F.3d 1426 (6th Cir. 1997); *Sutowski v. Eli Lilly & Co.*, 696 N.E. 2d 187 (Ohio 1998). *See also* Ohio Revised Code Section 2307.71 *et seq.*

Here, both Pamela and Kenneth Silvey are making their newfound claim of "product exposure," despite their own *specific denials* of such an exposure during the events in question, and despite the contemporaneous medical records, which all contradict plaintiffs' "product exposure" claim. Moreover, plaintiffs have testified that the remaining product was discarded, so the allegedly-ingested product itself is unavailable to corroborate plaintiffs' usage claims. (Pamela Silvey depo. at pp. 121, 139-40, Exhibit B.) And, when questioned about *which* SmithKline product plaintiff allegedly ingested during her deposition, Mrs. Silvey could not say for sure which product she used. (*Id.* at pp. 149-151.) Many Contac® products never contained PPA, and Mrs. Silvey was unable to testify with any certainty that she ingested PPA-containing Contac®. (*Id.* at pp. 138, 141, 149-151.) Nor did Mrs. Silvey read the back of the product box, so she was unable to determine if "phenylpropanolamine" even was listed as an ingredient in the Contac® she now claims to have taken years ago. (*Id.* at p. 131.)

In short, plaintiffs have no evidence that Pamela Silvey used PPA-containing Contac® at the time of her stroke. All of the evidence is to the contrary. Her newfound claim that she did ingest this product does not satisfy her burden in the face of the compelling evidence to the contrary.

C. The Evidence Overwhelmingly Establishes That Mrs. Silvey *Did Not Use* SmithKline's Product.

The overwhelming weight of the evidence establishes that Mrs. Silvey *did not use* a SmithKline PPA-containing product during the events in question. First, the contemporaneous (and undisputed) medical records show that no such medication was taken. Mrs. Silvey's treating physician, Dr. Van Loveren, testified as follows regarding the event in question, as documented in these contemporaneous medical records:

> Q: Doctor, does the St. Bernard emergency medical service record indicate in terms of history whether Mrs. Silvey had been taking any medications that day?
>
> A: It says **none**.

(Dr. Van Loveren depo. at p. 8, Exhibit A.)

> Q: Okay. The second document you have in front of you, Doctor, is a page from the emergency medical records from Good Samaritan Hospital.
>
> Q: And is this piece of paper, which we have marked as Exhibit 3 on the sticker, is this where some of the doctors in the emergency room would write down the results of their history and physical examination of Mrs. Silvey?
>
> A: Yes.
>
> Q: And have those doctors indicated whether, according to the history they obtained, Mrs. Silvey was taking any medications of any type on that day?
>
> A: **There's no medications**.
>
> Q: And what I am showing you now is Exhibit 4, which, again, is a copy of the emergency room or Trauma History and Physical Form taken at Good Samaritan. Does that also appear to be from January 15, 1998?
>
> A: Yes.
>
> Q: And on this document do these doctors indicate the results of that history as to whether Mrs. Silvey was taking any medications that day?
>
> A: They indicate that **she was not taking any medications that day**.

Q: When a doctor takes a history from a patient, we discussed the importance of being thorough, when they ask her about medications, in your experience, do doctors typically ask about **both prescription and nonprescription medications?**

A: Yes.

Q: Doctor, in terms of the history that the trauma doctors elicited on January 15th, 1998 at Good Samaritan, does it indicate who gave the history on that day, the Past Medical History section?

A: It says Past Medical History was obtained from the patient's husband.

Q: And does the history as obtained from the husband on this record indicate the results of the question as to whether she was taking any medications whatsoever that day?

A: Is says **medications, none**.

(Dr. Van Loveren depo. at pp. 8-12, Exhibit A)(emphasis added).

Q: Exhibit 5 appears to be another history and physical examination results form. Is this a form that is filled out at the hospital when a patient is admitted?

Q: Doctor, is page 265 of Defense Exhibit 5 an anesthesia evaluation done January 15, 1998 for Mrs. Silvey?

A: Yes.

Q: And is this yet another piece of paper where the doctors wrote the results of their history and physical examination on that date?

A: Yes.

Q: And what was, according to this piece of paper, the results of their question as to whether Mrs. Silvey had been taking any medications?

A: **No medications were taken that day.**

(Dr. Van Loveren depo. at pp. 12-14, Exhibit A)(emphasis added).

Q: Doctor, do you find any reference in Mrs. Silvey's medical records from the entire hospitalization from January and February of 1998 that would indicate that she ever took any medication with phenylpropanolamine in the two weeks before January 15, 1998?

A: **No**.

(Dr. Van Loveren depo. at p. 37, Exhibit A)(emphasis added).

These contemporaneous medical records are consistent with the testimony and documents authored by research nurse Laura Sauerbeck, R.N. (*See* Questionnaires, attached as Exhibit E, which were authenticated and also attached as Exhibits to Nurse Sauerbeck's deposition.) Nurse Sauerbeck personally performed the detailed interviews with plaintiffs Pamela and Kenneth Silvey on February 13-14, 1998 regarding medication use. Nurse Sauerbeck's interviews were conducted with the specific intent of determining whether Mrs. Silvey had actually used a PPA-containing product prior to her stroke. Nurse Sauerbeck's undisputed documentary evidence and testimony also show that *no such medication was taken.* Nurse Sauerbeck testified as follows:

> Q: Now, there is a subject interview questionnaire form that you would have filled out in the course of interviewing Mrs. Silvey; am I right about that?
>
> A: Correct.
>
> Q: And it says that the date of the interview was February 13, 1998; is that right?
>
> A: Yes.

(Nurse Sauerbeck depo. at pp. 27-28, Exhibit D.)

> Q: And then after finding, getting no's to all of those questions, what's the next question you asked?
>
> A: "Now I would like you to try to recall any medication you may have used during this time period. Please look at the calendar again and take a minute to think about any other medications or drugs you may have taken on the index date or on the three days before that date or at any time during these two weeks. We are interested in any medication you may have taken, **including those prescribed by a doctor or that you bought over-the-counter**."
>
> Q: And what did she answer to that?
>
> A: She -- I have **none recalled.** So I don't know what her exact words were but --
>
> Q: She answered -- What were the choices that she could have given you?

A: She could have listed any medications that she recalled.

Q: You circled here none recalled?

A: Uh-huh.

(Nurse Sauerbeck depo. at p. 33, Exhibit D)(emphasis added).

Q: And were there additional questions about specific medications?

A: Yes.

Q: And what was that question?

A: "Now I would like to review some specific medications you may have taken during this time period. Did you take," and then I would ask aspirin, get a response; then I would go on to acetaminophen and give an example, such as Tylenol; anti-inflammatories, such as Advil, Motrin, Naprosyn, or Feldene; blood thinners, such as Coumadin; asthma medications, an inhaler, Theophylline, or Prednisone; medications for depression, such as Marplan, Nardil, or Parnate; or hemorrhoidal preparations.

Q: And her answer for all of those questions as to those medications being taken or not was what?

A: No.

(Nurse Sauerbeck depo. at pp. 34-35, Exhibit D.)

Q: And she didn't indicate that she had taken any medication, correct?

A: Correct.

Q: And her husband didn't indicate that she had taken any medication, correct?

A: Correct.

(Nurse Sauerbeck depo. at p. 78, Exhibit D.)

When plaintiff Kenneth Silvey was extensively interviewed at his home on February 14, 1998, *he also denied* that his wife Pamela had been taking any medications, prescription or over-the-counter, in the two weeks prior to her stroke:

Q: Following up on the interview of Mrs. Silvey, did you have occasion to interview her husband, Kenneth Silvey?

A: Yes.

Q: So you would have done this interview of Mr. Silvey at his home?

A: Yes.

Q: During the course of the interview of Mr. Silvey you also filled out a questionnaire?

A: Yes.

Q: And the questionnaire records his responses to you of the question that you asked about his wife?

A: Correct.

Q: Did Mr. Silvey indicate that his wife or recall that his wife had taken any medication during that two-week period of time?

A: This indicates that **none was recalled**.

(Nurse Sauerbeck depo. at pp. 40-43, Exhibit D)(emphasis added).

In summary, an evaluation of the product identification *evidence* in this case, and the inferences drawn therefrom, leads to the conclusion that summary judgment should be granted. (*See* table below.) Mrs. Silvey's contradictory memory regarding product identification does not raise a genuine issue of material fact when compared to the undisputed contemporaneous evidence:

PLAINTIFFS' CLAIM	**vs.**	**EVIDENCE SHOWING NO PRODUCT USE**
Plaintiff's uncertain and uncorroborated claim, 2 years and ten months after the events in question, and after viewing a plaintiff's lawyer's commercial on television for PPA lawsuits, that she used defendant's PPA-containing product. (Exhibit B, pp. 94-95; 100-101)		Yale study questionnaire completed on behalf of plaintiff Pamela Silvey on February 13, 1998, and witnessed by Laura Sauerbeck, R.N. (Exhibit E)
		Yale study questionnaire completed on behalf of plaintiff Kenneth Silvey on February 14, 1998 and witnessed by Laura Sauerbeck, R.N. (Exhibit E)
		St. Bernard Emergency Medical Service records dated January 15, 1998 (Exhibit A appendix)

	Good Samaritan Hospital Emergency Department records dated January 15, 1998 (Exhibit A appendix)
	Good Samaritan Hospital Trauma records dated January 15, 1998 (Exhibit A appendix)
	Good Samaritan Hospital Anesthesia records dated January 15, 1998 (Exhibit A appendix)
	Sworn testimony of plaintiff's treating physician, Dr. Van Loveren (Exhibit A)
	Sworn testimony of Laura Sauerbeck, R.N., who interviewed both Pamela and Kenneth Silvey regarding medication use on February 13-14, 1998 (Exhibit D)
	Product itself was discarded by plaintiff and/or her family member (Exhibit B, pp. 129, 139-140)
	Plaintiff's admission that she did not read the back of the product packaging, where the "ingredients" would be listed. (Exhibit B, pp. 130-131)

Under these circumstances, no reasonable jury could find for the plaintiff on the issue of product use. This lack of credible product usage evidence defeats all five Counts in plaintiffs' Complaint. *See Anjeski v. ACandS Inc.*, No. 89-1571, 1990 WL 58191, at **4 (6th Cir. May 7, 1990)(Exhibit F).

D. Plaintiffs' Explanation For Their Lack of Evidence Is Not Credible.

Plaintiffs may argue that Mrs. Silvey had poor memory at the time of her Yale Study interview in February of 1998 due to her medical condition, and that three years later, after viewing the television advertisement by a plaintiff's PPA firm, she finally "remembered" that she had used a specific PPA-containing product back in January of 1998. However, this after-the-fact and contradictory "remembering" could not possibly convince a reasonable jury -- and should not be permitted.

First, as part of the detailed interviews conducted by Nurse Sauerbeck in February of 1998, multiple questions were asked to determine whether the interviewee had adequate memory and was fully lucid and alert to respond appropriately. Through these questions, both Pamela Silvey and Kenneth Silvey were deemed fully alert and able to answer all questions appropriately:

> Q: Did you rate her [Pamela Silvey's] language ability during the interview?
>
> A: Yes.
>
> Q: And what did you rate it as?
>
> A: Her language ability on the subject during interview is no language problem.
>
> Q: Did you rate your confidence in the ability of Mrs. Silvey to give you an accurate history?
>
> A: Yes, I did.
>
> Q: Okay. And what did you rate Mrs. Silvey in terms of your confidence, having just completed the interview, in her ability to give you an accurate history?
>
> A: Confident.

(Nurse Sauerbeck depo. at pp. 39-40, Exhibit D.)

> Q: Mrs. Sauerbeck, in conducting the interview of Mrs. Silvey and in filling out the questionnaire, asking her the questions, listening to her responses, did you determine that she was cognitively impaired and incapable of answering the questions in the questionnaire?
>
> MRS. ABARAY: Objection, compound.
>
> A: Based on the screening, which was our criteria to say whether or not somebody could, was cognitive enough, she passed the test, and so she was acceptable to be interviewed.

(Nurse Sauerbeck depo. at p. 76, Exhibit D.)

> Q: Upon completing his [Kenneth Silvey's] questionnaire did you also fill out an interviewer observation form for the questions?

A: Yes.

Q: And how did you rate your confidence in the ability of Mr. Silvey to give you an accurate history regarding his wife?

A: Confident.

Q: Was there any language difficulty during the course of the interview?

A: No.

(Nurse Sauerbeck depo. at p. 44, Exhibit D.)

In fact, the record of Mrs. Silvey's February, 1998 interview, as documented by Nurse Sauerbeck in the research case file, shows that Mrs. Silvey had a very vivid memory of the events occurring prior to her stroke:

Q: Would you please read to us what you wrote down in information that you obtained from both the case [Pamela Silvey] and from the proxy [Kenneth Silvey] under the symptoms?

A: "Case doesn't remember feeling ill on 1/15/98. Left for work at approximately 6 a.m. Was smoking a cigarette and drinking coffee at time. That's the last thing that case remembers."

(Nurse Sauerbeck depo. at p. 26, Exhibit D.) On that interview day, Mrs. Silvey also specifically and correctly remembered the number of cigarettes she had smoked in the days leading up to her stroke, the number of cups of coffee she had drunk during that time, her history of heavy bleeding, her history of migraine headaches, her job title, age, the current month, etc. (*See* Exhibit E.)

Second, plaintiffs' excuse that "Mrs. Silvey's health" temporarily erased her memory of medication use does not explain why Mrs. Silvey's *husband*, Kenneth Silvey, *also denied* that Mrs. Silvey had been using any medication when he was extensively interviewed in February of 1998. Third, plaintiff's explanation also cannot dispute the unanimous weight of the contemporaneous medical records, which all show that Mrs. Silvey was not taking any medications during the events in question. *See* citations, *supra*.

In this case, the implausible and contradictory claim by plaintiffs amounts to a "scintilla of evidence" at best, and should not preclude summary judgment. *See, e.g. Knotts v. Black & Decker*, 204 F. Supp. 2d 1029, FN 6 (N.D. Ohio 2002) ("Conflicts between affidavits and other evidentiary materials do not preclude summary judgment and the court may disregard the subsequent affidavit unless a legitimate reason is given for the discrepancy."); *Wexler v. White's Fine Furniture*, 317 F.3d 564 (6th Cir. 2003) ("The party opposing summary judgment must present significant probative evidence, not merely colorable evidence, which is sufficient to create more than some metaphysical doubt as to the material facts. ..[].. The summary judgment paradigm requires a court to draw and respect only reasonable inferences; a court need not regard that which is farfetched or fantastic.") Plaintiff has simply failed to raise a *genuine* issue of fact on the necessary element of product use.

E. Plaintiffs' "Failure To Warn" Claims Also Fail Because Mrs. Silvey Did Not Read The Warning Label.

Plaintiff Pamela Silvey conceded that she did not read the warnings on the Contac® that she allegedly ingested. (Pamela Silvey depo. at pp. 130-131, Exhibit B.) Therefore, even if this Court believes that plaintiffs' unbelievable claim of product use precludes summary judgment, plaintiffs' "failure to warn" claims[2] must be dismissed.

Under Ohio law, in "failure to warn" cases, it is the plaintiff's burden to prove that the manufacturer's warnings were inadequate and that those inadequate warnings were the cause of plaintiff's injuries. *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 838 (Ohio 1981). When the plaintiff is unable to demonstrate a genuine issue of material fact involving the adequacy of the warnings, the manufacturer is entitled to summary judgment on those claims. *See Skerl v. Arrow Int'l, Inc*., 202 F. Supp.2d 748 (N.D. Ohio 2001). In *Seley*, the Ohio Supreme Court adopted a two-

[2] Plaintiff's "failure to warn" claims are scattered in their First, Second and Fifth Causes of Action in their Complaint.

fold test when analyzing proximate cause in failure to warn cases - the plaintiff must prove (1) that the lack of adequate warnings contributed to the plaintiff's ingestion of the drug; and (2) that the ingestion of the drug constitutes a proximate cause of the plaintiff's injury. *Seley, supra*, following *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (Oregon 1974).

Ohio courts have held that a plaintiff *cannot establish* this causation element of a failure to warn claim if he or she did not read the warnings. *See, e.g. Phan v. Presrite Corp*., 653 N.E.2d 708 (Ohio App. 1994); *Mitten v. Spartan*, No. 13891, 1989 WL 95259 (Ohio App. 1989)(Exhibit G.)[3]

In *Phan*, Ohio's 8th Appellate District affirmed summary judgment in favor of the defendant manufacturer on the failure to warn claims based on the plaintiff's failure to read the product warnings. The *Phan* Court held that the plaintiff failed to present any evidence that the alleged inadequacy of the warnings caused his injuries because, even if the additional warnings suggested by the plaintiff's expert were included in the product warnings, they would not have prevented the injuries *as plaintiff did not read the warnings*. *Phan*, 653 N.E.2d at 711.

Here, plaintiff can present no evidence that the alleged inadequacy of the Contac® product warnings was the cause of her injuries because she admittedly did not read the warning labels provided with the product:

> Q. Did you read the warning labels on the box before you took the medication?
>
> MR. TREGRE: Objection.
>
> A. No.
>
> Q. I didn't hear your answer.
>
> A. The only thing I ever looked for ingredients, you know, on anything is aspirin because I'm allergic to aspirin.

[3] The 6th Circuit has recognized that the presumption set forth in the Restatement (Second) of Torts § 402A cmt. j (that adequate warnings are presumed to have been read and heeded, and inadequate or no warnings are presumed to be the proximate cause of the plaintiff's use of the product), is rebutted when there is direct evidence that the plaintiff did not read the warnings or instructions. *Hisrich v. Volvo*, 226 F.3d 445, 451 (6th Cir. 2000), following *Phan*, supra.

Q. I didn't hear your answer, did you or did you not read the warning labels on the Contac that you took in January of '98?

A. No, because there wasn't, you know, I know I don't have high blood pressure of anything like that, so I never did read it.

(Pamela Silvey depo. at pp. 130-131, Exhibit B.)

Here, like *Phan*, plaintiffs may assert that additional warnings related to strokes should have been provided with the Contac® packaging. However, as the Court found in *Phan*, any such suggested warnings would not have made any difference because Mrs. Silvey admittedly did not read the warnings. Thus, plaintiffs cannot establish that the Contac® warnings contributed to Mrs. Silvey's ingestion of the drug -- the necessary proximate cause element of their failure to warn claim. Therefore, as to plaintiffs' failure to warn claim, no genuine issue of material fact exists and SmithKline is entitled to judgment as a matter of law.

III. CONCLUSION

On balance, reasonable jurors could only interpret the evidence as establishing that Mrs. Silvey *did not use* defendant's PPA-containing product during the events in question. Her testimony to the contrary is "farfetched and fantastic." *See Wexler, supra.* All of the contemporaneous evidence, including detailed interviews and questionnaires obtained from both plaintiffs regarding medication use, the testimony of plaintiff's own physician, the testimony of research nurse Laura Sauerbeck, and the medical records themselves, establishes that Mrs. Silvey did not use defendant's PPA-containing product. Under these circumstances, reasonable jurors could come to but one conclusion -- a conclusion adverse to plaintiffs -- entitling defendant SmithKline Beecham Corp. to judgment as a matter of law. Alternatively, even if plaintiffs' unlikely claim of product use raises a genuine issue of material fact, defendant is nonetheless entitled to summary judgment on plaintiffs' failure to warn claim, because Mrs. Silvey admitted that she did not read the warning label. Two

separate Proposed Findings of Fact and Conclusions of Law reflecting this requested relief are attached hereto for the Court.

Respectfully submitted,

/s/ ROBERT C. TUCKER
ROBERT C. TUCKER, Trial Attorney (0013098)
email: rtucker@tuckerellis.com
EDWARD E. TABER (0066707)
email: etaber@tuckerellis.com
TUCKER ELLIS & WEST LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, OH 44115-1475
Telephone: (216) 592-5000
Telefax: (216) 592-5009

Counsel for defendant SmithKline Beecham Corp.

PROOF OF SERVICE

I hereby certify that on this 5th day of October 2004 a copy of the foregoing Defendant's Motion for Summary Judgment and Memorandum in Support of Defendant's Motion for Summary Judgment was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system to:

Janet G. Abaray, Esq. — *Attorney for Plaintiffs*
Calvin S. Tregre, Jr., Esq.
Lopez, Hodes, Restaino, Milman,
& Skikos
312 Walnut Street - Suite 2090
Cincinnati, OH 45202

/s/ ROBERT C. TUCKER
One of the Attorneys for Defendant
SmithKline Beecham Corp.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PAMELA S. SILVEY, et al., Plaintiffs, v. SMITHKLINE BEECHAM CORP., Defendant.	)	CASE NO. C-1-01-164 JUDGE HERMAN J. WEBER **DEFENDANT SMITHKLINE BEECHAM CORP.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

Defendant SmithKline Beecham Corp. (SmithKline), submits the following Proposed Findings of Fact and Conclusions of Law to accompany SmithKline's Motion for Summary Judgment, filed October 5, 2004.

INTRODUCTION

This pharmaceutical product liability action was filed by plaintiffs Pamela and Kenneth Silvey in the United States District Court, Southern District of Ohio (Cincinnati) on March 19, 2001. There is one defendant -- SmithKline Beecham Corp. Plaintiffs claim that SmithKline's Contac® cold medicine caused her to have a stroke on January 15, 1998 – a claim which SmithKline refutes. On September 27, 2001 this Court entered a stay of proceedings, and shortly thereafter this case was transferred to the United States District Court, Western District of Washington for multi-district litigation pretrial proceedings with Judge Barbara Jacobs Rothstein. (MDL No. 1407). The case was remanded back to this Court by an Order filed on March 16, 2004.

FINDINGS OF FACT

1. Plaintiff Pamela Silvey was taken by ambulance to Good Samaritan Hospital in Cincinnati on the morning of January 15, 1998, after being involved in a motor vehicle accident. She was admitted to the hospital though the emergency department, and was diagnosed with a type of stroke known as an aneurysmal subarachnoid hemorrhage. Mrs. Silvey's treating neurosurgeon was Harry Van Loveren, M.D.

2. In the course of Mrs. Silvey's January 15th to February 27th, 1998 admission to the hospital, both she and her husband, Kenneth Silvey, were interviewed multiple times by different medical personnel regarding whether Mrs. Silvey had been ill prior to her stroke, and whether she had been taking any prescription and non-prescription medications prior to her stroke. These records uniformly indicate that Mrs. Silvey had not been ill prior to her stroke, and that she had not been taking any medication of any type prior to her stroke.

3. On February 13, 1998, Ms. Silvey voluntarily enrolled and consented to participate in medical studies conducted by neurologist Joseph Broderick, M.D. and Research Nurse Laura Sauerbeck, R.N.

4. On February 13, 1998, Dr. Broderick's research nurse, Laura Sauerbeck, R.N., interviewed Ms. Silvey and a questionnaire was completed regarding whether Mrs. Silvey had been taking any prescription or non-prescription medications prior to her stroke, and whether Mrs. Silvey had experienced any cold symptoms or other illness in the two weeks prior to her stroke. The following day, on February 14, 1998, Nurse Sauerback interviewed Mrs. Silvey's husband, Kenneth Silvey, and a similar questionnaire was completed using similar questions. Both interviews were personally conducted by Nurse Sauerbeck. Prior to completing both interviews, Nurse Sauerbeck conducted a standardized series of questions to determine whether the interviewee was mentally competent to answer the questions. Nurse Sauerbeck contemporaneously documented that she was

"confident" that both Mr. Silvey and Mrs. Silvey were competent to appropriately answer the interview questions.

5. During these February 1998 interviews, both plaintiffs indicated that Mrs. Silvey had not been experiencing any cold symptoms in the two weeks prior to her stroke. During the interviews, both plaintiffs stated that they could not recall Mrs. Silvey using any prescription or non-prescription medications of any type prior to her stroke. Nurse Sauerbeck contemporaneously documented this information in Ms. Silvey's medical research case file.

6. Ms. Silvey made a full recovery from her stroke, and claims no residual physical or emotional injuries as a result of the stroke.

7. Nearly three years later, in November of 2000, Ms. Silvey received a letter from Dr. Broderick thanking her for her participation in his medical studies and noting that his research might indicate a potential link between some medications and stroke.

8. Shortly after receiving Dr. Broderick's November 2000 letter, Ms. Silvey viewed a television commercial advertising PPA litigation claims against various pharmaceutical companies. Ms. Silvey then retained counsel and filed the instant lawsuit, wherein she now claims that she suffered severe cold symptoms immediately prior to her January 15, 1998 stroke, for which she purchased and ingested Contac® cold medicine containing phenylopropanolamine.

CONCLUSIONS OF LAW

1. Pursuant to Fed. R. Civ. P. 56(c), summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. A genuine issue for trial exists when there is sufficient "evidence on which the jury could reasonably find for the plaintiff." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

2. "The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be a genuine issue of material fact." *Anderson,* 477 U.S. at 248 (1986). In considering a motion for summary judgment "a mere…scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson,* 477 U.S. at 252. Summary judgment may be granted if the evidence is "merely colorable, or is not significantly probative." *Anderson,* 477 U.S. at 249-50.

3. This Court has reviewed the following materials which have been provided either as exhibits to deposition transcripts or attached to the parties' corresponding motions: (1) the sworn deposition testimony of Plaintiff Pamela S. Silvey, treating neurosurgeon Harry Van Loveren, M.D. and research nurse Laura Sauerbeck, R.N.; (2) portions of Ms. Silvey's medical records which were appended to those depositions, and referenced therein; (4) the medical research study questionnaire completed by Nurse Sauerbeck on behalf of Mrs. Silvey on February 13, 1998, and a similar questionnaire completed by Nurse Sauerbeck on behalf of Mr. Silvey on February 14, 1998.

4. Based on the Court's review of these materials, all of the contemporaneous evidence establishes that Mrs. Silvey did not ingest defendant's product. Product identification is an essential element of plaintiffs' burden of proof. Plaintiffs have failed to raise a genuine issue of material fact such that reasonable minds could find that plaintiffs have met their burden on this issue. Reasonable minds could come to but one conclusion on this issue – a conclusion adverse to plaintiffs. Plaintiffs' claim of product use, with no corroborating evidence whatsoever, and in the face of overwhelming evidence to the contrary, constitutes no more than a scintilla of evidence. *See Anderson,* 477 U.S. at 252.

ORDER

Accordingly, the Court GRANTS defendant's Motion for Summary Judgment as to all of plaintiffs' claims herein.

IT IS SO ORDERED.

_____ _____

JUDGE HERMAN J. WEBER DATE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PAMELA S. SILVEY, et al., Plaintiffs, v. SMITHKLINE BEECHAM CORP., Defendant.	CASE NO. C-1-01-164 JUDGE HERMAN J. WEBER **DEFENDANT SMITHKLINE BEECHAM CORP.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AS TO ALL FAILURE TO WARN CLAIMS ONLY**

Defendant SmithKline Beecham Corp. (SmithKline), submits the following Proposed Findings of Fact and Conclusions of Law to accompany SmithKline's Motion for Summary Judgment, filed October 5, 2004.

INTRODUCTION

This pharmaceutical product liability action was filed by plaintiffs Pamela and Kenneth Silvey in the United States District Court, Southern District of Ohio (Cincinnati) on March 19, 2001. There is one defendant -- SmithKline Beecham Corp. Plaintiffs claim that SmithKline's Contac® cold medicine caused her to have a stroke on January 15, 1998 – a claim which SmithKline refutes. On September 27, 2001 this Court entered a stay of proceedings, and shortly thereafter this case was transferred to the United States District Court, Western District of Washington for multi-district litigation pretrial proceedings with Judge Barbara Jacobs Rothstein. (MDL No. 1407). The case was remanded back to this Court by an Order filed on March 16, 2004.

FINDINGS OF FACT

1. Plaintiff Pamela Silvey provided deposition testimony on December 18, 2002. During this testimony, she explicitly admitted that she did not read any of the warnings on the product in question - Contac® cold medicine.

CONCLUSIONS OF LAW

1. In "failure to warn" product liability claims, plaintiff has the burden to prove that the manufacturer's warnings were inadequate and that those inadequate warnings were a producing cause of plaintiff's injuries. *Seley v. G.D. Searle & Co*., 423 N.E.2d 831, 838 (Ohio 1981). When the plaintiff is unable to demonstrate a genuine issue of material fact involving the adequacy of the warnings, the manufacturer is entitled to summary judgment on those claims. *See Skerl v. Arrow Int'l, Inc*., 202 F. Supp.2d 748 (N.D. Ohio 2001).

2. In *Seley*, the Ohio Supreme Court adopted a two-fold test when analyzing proximate cause in failure to warn claims - the plaintiff must prove (1) that the lack of adequate warnings contributed to the plaintiff's ingestion of the drug; and (2) the ingestion of the drug constitutes a proximate cause of the plaintiff's injury. *Seley*, *supra*, following *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (Oregon 1974).

3. Several Ohio courts have held that a plaintiff cannot establish this causation element of a failure to warn claim if he or she did not read the warnings. *See, e.g. Phan v. Presrite Corp*., 653 N.E.2d 708 (Ohio App. 1994); *Mitten v. Spartan*, No. 13891, 1989 WL 95259 (Ohio App. 1989).

4. Here, plaintiff Pamela Silvey's admission that she did not read the warning label on the product in questions defeats plaintiffs' failure to warn claims. Defendant has affirmatively

demonstrated that plaintiff cannot meet an essential element of their burden of proof, as to the failure to warn claims.

ORDER

Accordingly, the Court GRANTS defendant's Motion for Summary Judgment as to all of plaintiffs' failure to warn claims only.

IT IS SO ORDERED.

_____ _____

JUDGE HERMAN J. WEBER DATE

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